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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/027,777	02/23/1998	HANSUELI IMMER	P108099-00001	3626
7590	04/21/2004			

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/027,777	<b>Applicant(s)</b> IMMER ET AL.	
	<b>Examiner</b> Ron Schwadron, Ph.D.	<b>Art Unit</b> 1644	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-37 is/are pending in the application.  
     4a) Of the above claim(s) 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/737927.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

1. Claims 36 and 37 are under consideration.

#### RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for claim 37. Applicant has not indicated where said claim finds support in the specification as originally filed. The claim encompasses the recited peptide purified by any art known procedure that would result in variable degrees of purity (eg. low or medium), yet there is no disclosure of the scope of such purified peptides in the specification as originally. There is no written description of the scope of the claimed invention in the specification as originally filed (eg. the claimed invention constitutes new matter).

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 36 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Forssmann et al. (EP 0349545) as evidenced by Nutt et al. (US Patent 5,057,603). Applicants arguments have been considered and deemed not persuasive.

Forssmann et al. teach the peptide recited in claim 36(b) except for the AcM molecule attached to the first Cys (see page 9). Forssmann et al. teach that said peptide would be made using chemical synthetic means using protected amino acid groups including Cys (AcM) (see page 10, Example 3). Forssmann et al. teach that the peptide containing the protective groups is treated with HF (see page 10, Example 3). It is an inherent property of said treatment that it would remove all the protective groups except Cys (AcM) (see Nutt et al., column 8, last paragraph). Therefore, said treatment would yield a peptide that differed from the claimed peptide by having two Cys(AcM). Forssmann et al. teach that the peptide containing the two Cys(AcM) is treated to remove AcM (see page 10, last paragraph of Example 3). Since it would be physically impossible for the two AcM molecules to be removed at exactly the same time, it would be expected that treatment would yield a mixture of peptides containing one Cys(AcM) at either residue (before all residues were removed to yield Cys residues free of AcM). The transiently occurring peptide with Cys(AcM) at the first residue of the peptide is the claimed invention and would be expected to occur prior to the formation of Cys(AcM) free peptide. The peptide is purified to the extent that the starting material (peptide pretreatment) was already purified (see page 9).

Regarding applicants comments, applicant has referred to several references that were not of record or submitted, so applicants comments regarding said references have not been considered. Regarding the various other assertions made by applicant, the MPEP section 716.01(c) states:

**ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE**

*The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial*

*success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.*

In addition, applicants arguments ignore the fact that the claimed peptide has Cys residues in different regions wherein the secondary structure and the adjoining amino acid residues would determine the accessibility of the Cys residues to AcM removal (at least initially). Since it would be physically impossible for the two AcM molecules to be removed at exactly the same time, it would be expected that treatment would yield a mixture of peptides containing one Cys(AcM) at either residue (before all residues were removed to yield Cys residues free of AcM). The transiently occurring peptide with Cys(AcM) at the first residue of the peptide is the claimed invention and would be expected to occur prior to the formation of Cys(AcM) free peptide.

6. No claim is allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the

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examiner's supervisor, Christina Chan, can be reached at 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1644